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Novartis Vaccines and Diagnostics Inc.  
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In re Application of :  
RAPPUOLI :  
Application No.: 10/568,422 :  
PCT No.: PCT/US04/30032 :  
Int. Filing Date: 15 September 2004 :  
Priority Date: 15 September 2003 :  
Attorney Docket No.: 002441.00189 :  
For: IMMUNOGENIC COMPOSITIONS FOR :  
STREPTOCOCCUS AGALACTIAE :

DECISION ON REQUEST

This decision is issued in response to applicants' "Response to Notification of Missing Requirements" filed 22 October 2007, which is being treated as a request under 37 CFR 1.497(d) to correct the inventorship of the present national stage application. Deposit Account No. 19-0033 has been charged the required processing fee.

**BACKGROUND**

On 15 September 2004, applicants filed international application PCT/US04/30032 which claimed a priority date of 15 September 2003. The published international application identified one applicant/inventor for the United States: Rino Rappuoli. The deadline for submission of the basic national fee was to expire thirty months from the priority date, 15 March 2006.

On 14 February 2006, applicants filed a transmittal letter for entry into the national stage in the United States accompanied by, among other materials, payment of the basic national fee.

On 22 March 2007, the United States Designated Office (DO/EO/US) mailed a Notification Missing Requirements under 35 U.S.C. 371 (Form PCT/DO/EO/905) indicating that a signed oath/declaration of the inventors in compliance with 37 CFR 1.497(a) and (b) together with a surcharge payment were required. Furthermore, the Notification indicated that a Sequence Listing had not been filed as required by 37 CFR 1.821(c) and (e). The notification set a two-month time limit in which to respond.

On 22 October 2007, applicants submitted the present request and a declaration executed by: John Telford, Guido Grandi, Immaculada Margarit Y. Ros, and Domenico Maione.<sup>1</sup>

### DISCUSSION

As defined in 37 CFR 1.9(a)(3), a U.S. national stage application must first comply with the requirements of 35 U.S.C. 371(c) to constitute a "nonprovisional" application, therefore, applicants' request will be treated under 37 CFR 1.497(d). The present submission seeks to correct the inventorship so as to add inventors John Telford, Guido Grandi, Immaculada Margarit Y. Ros, and Domenico Maione to the application. Additionally, applicant requests to delete Rino Rappuoli as an applicant/inventor. Where, as here, the inventorship in the national stage declaration is not consistent with the inventorship in the international application, applicants must correct the inventorship pursuant to 37 CFR 1.497(d), which states the following:

(d) If the oath or declaration filed pursuant to 35 U.S.C. 371(c)(4) and this section names an inventive entity different from the inventive entity set forth in the international application, the oath or declaration must be accompanied by:

(1) A statement from each person being added as an inventor and from each person being deleted as an inventor that any error in inventorship in the international application occurred without deceptive intention on his or her part;

(2) The processing fee set forth in § 1.17; and

(3) If an assignment has been executed by any of the original named inventors, the written consent of the assignees (see § 3.73(b) of this chapter).

(4) any new oath or declaration required by paragraph (f) of this subsection.

With respect to item (1), applicants have submitted statements from the inventors being added, John Telford, Guido Grandi, Immaculada Margarit Y. Ros, and Domenico Maione, in which the inventors state that the earlier error in inventorship occurred without any deceptive intent on his/her part. Further, applicants have submitted a statement from the inventor being removed, Rino Rappuoli, in which the inventor states that the error in inventorship occurred without any deceptive intent on his part. Item (1) is therefore satisfied.

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<sup>1</sup>Applicants' submission included a copy of the sequence listing (paper copy and computer readable form) previously filed on 14 February 2006.

With respect to item (2), applicants have submitted the required \$130 processing fee. Item (2) is therefore satisfied.

With respect to item (3), applicants state that Rino Rappuoli did not execute an assignment, therefore, a consent of the assignee is not required. Item (3) is therefore satisfied.

Item (4) does not apply to the present application.

Accordingly, applicants have satisfied all the requirements for correction of inventorship under 37 CFR 1.497(d).

### **CONCLUSION**

Applicants' request for correction of inventorship under 37 CFR 1.497(d) is **GRANTED**.

John Telford, Guido Grandi, Immaculada Margarit Y. Ros, and Domenico Maione are added as inventors herein. Rino Rappuoli has been deleted as an inventor.

This application is being forwarded to the National Stage Processing Branch of the Office Of PCT Operations for further processing in accordance with this decision.



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